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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,512	09/30/2003	Brian Keith Wells	10121/03501	4114
30636	7590	12/03/2004	EXAMINER	
FAY KAPLUN & MARCIN, LLP 150 BROADWAY, SUITE 702 NEW YORK, NY 10038			KASZTEJNA, MATTHEW JOHN	
			ART UNIT	PAPER NUMBER

3739

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/674,512	Applicant(s) WELLS ET AL.	
	Examiner Matthew J Kasztejna	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/30/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because of the poor quality of the drawings. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Method claims 35-36 are dependent upon claim 26 which is an apparatus claim. For examination purposes, it is assumed both claims are dependent upon claim 28.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 4-5, 15, 28-30 and 32-35 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent Publication No. 2003/0069592 to Adams et al.

In regards to claim 1, Adams et al. disclose an apparatus for deployment of a hemostatic clip comprising: a handle (Fig. 7); a shaft connecting to the distal portion of the handle; a clip assembly 101 releasable coupled to the distal portion of the shaft, the clip having arms 102 and 103 and a capsule 111 which is capable of providing a first user feedback indicating the clip configuration; and a control wire 1207 including a ball connector 1202, the control wire extending from the handle assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, wherein the ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft (see. Figs 12a and 12b).

In regards to claim 2, Adams et al. disclose an apparatus for deployment of a hemostatic clip having a sheath 1206 which is movable, relative to control wire 1207, to a first and second position of covering and uncovering the clip (see Paragraph 0072 and 0084).

In regards to claim 4, Adams et al. disclose an apparatus for deployment of a hemostatic clip wherein the clip arms further comprise stop shoulders 1203 engaging a distal end of the capsule to provide the first user feedback (see Paragraph 0084).

In regards to claim 5, Adams et al. disclose an apparatus for deployment of a hemostatic clip wherein the decision configuration indicates a position of the control wire beyond which further proximal movement of the control wire precludes return of the clip

arms to an open configuration by a reversed movement of the control wire. Adams et al. disclose of the ability to repeatedly open and close the clip until the tissue pinching is accomplished (see paragraph 0014).

In regards to claim 15, Adams et al. disclose an apparatus for deployment of a hemostatic clip wherein the first feedback is inherently capable of providing both tactile and aural feedback (see Paragraph 0084).

In regards to claim 28-30 and 32-36, the compress apparatus for deployment of a hemostatic clip of Adams et al. is considered to be inherently capable of the recited method steps.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 6-9, 12-14, 16 and 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication No. 2003/0069592 to Adams et al in view of U.S. Patent No. 4,733,664 to Kirsch et al.

In regards to claim 6-9, 12-14,16, 19-27, 31, Adams et al. disclose an apparatus for deployment of a hemostatic clip comprising: a handle (Fig. 7); a shaft connecting to the distal portion of the handle; a clip assembly 101 releasable coupled to the distal portion of the shaft, the clip having arms 102 and 103 and a capsule 111 which is capable of providing a first user feedback indicating the clip configuration; and

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a control wire 1207 including a ball connector 1202, the control wire extending from the handle assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, wherein the ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft but is silent with respect to a tension member releasably connected to the yoke and to the clips arms. Kirsch et al. teach of an analogous surgical clip wherein the center of the bridge is integrally connected to a tang 19 preferably having an enlarged head 20, and therefore is inherently capable of being releasably connected. The male and female c-sections can be seen in Fig. 3. The connection point is a neck 21 of reduced cross-section designed to break when a predetermined tension is applied to the tang by the tool. It would have been obvious to one skilled in the art at the time the invention was made to include a releasably connected yoke and tension member to the apparatus of Adams et al. so that the tension member produces a bending moment at the center of the bridge when a tension is applied and to enhance the bending abilities of the device of Adams et al., as taught by Kirsch et al.

5. Claims 3, 10-11 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication No. 2003/0069592 to Adams et al in view of U.S Patent No. 6,814,742 to Kimura et al.

In regards to claim 3, Adams et al. disclose an apparatus for deployment of a hemostatic clip comprising but is silent with respect to an over sheath stop engageable on the shaft to prevent movement of the over sheath. Kimura et al. teach of an

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analogous clipping apparatus having a stop tube 4 with protrusions 4a (see Fig. 1d). It would have been obvious to one skilled in the art at the time the invention was made to include a stop tube in the apparatus of Adams et al. in order to prevent further movement of the sheath once engaged, as taught by Kimura et al.

In regards to claim 10-11 and 17-18, Adams et al. disclose an apparatus for deployment of a hemostatic clip comprising but is silent with respect to the separation tension being at least 4 lbf. or less than 12 lbf. Kimura et al. teach of an analogous clipping apparatus wherein a tensile force of about 3kgf to 5kgf is applied to the linking member 3, so the link member breaks at the fracture section 3d (see Col. 9, Lines 60-62). It would have been obvious to one skilled in the art at the time the invention was made to provide a separation tension of 3-5 kgf in the apparatus of Adams et al. as it provides a sufficient range for breakage as taught by Kimura et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,049,153 to Nakao et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone

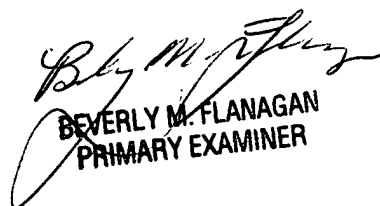
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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJK

11/15/04


BEVERLY M. FLANAGAN
PRIMARY EXAMINER